Defense Health Agency (DHA)
2022.1 Small Business Innovation Research Program (SBIR)
Proposal Submission Instructions

INTRODUCTION

The Defense Health Agency (DHA) SBIR Program seeks small businesses with strong research and development capabilities to pursue and commercialize medical technologies.

Broad Agency Announcement (BAA), topic, and general questions regarding the SBIR Program should be addressed according to the DoD SBIR Program BAA. For technical questions about a topic during the pre-release period, contact the Topic Author(s) listed for each topic in the BAA. To obtain answers to technical questions during the formal BAA period, visit https://www.dodsbirsttr.mil/submissions/login

The DHA Program participates in up to three DoD SBIR BAAs each year. Proposals not conforming to the terms of this BAA will not be considered. Only Government personnel will evaluate proposals with the exception of technical personnel from Odyssey Systems who will provide technical analysis in the evaluation of proposals submitted against DHA topic number:

- DHA221-001 - Prolonged Care: To Demonstrate a Medicated Combat Tourniquet Capable of Wound Infection Treatment Delivery.

Proposers responding to a topic in this BAA must follow all general instructions provided in the Department of Defense (DoD) SBIR Program BAA. DHA requirements in addition to or deviating from the DoD Program BAA are provided in the instructions below.

Specific questions pertaining to the administration of the DHA SBIR Program and these proposal preparation instructions should be directed to:

DHA SBIR Program Management Office (PMO)
Email - usarmy.detrick.medcom-usamrmc.mbx.dhpsbir@mail.mil
Phone - (301) 619-7296

PHASE I PROPOSAL GUIDELINES

The Defense SBIR/STTR Innovation Portal (DSIP) is the official portal for DoD SBIR/STTR proposal submission. Proposers are required to submit proposals via DSIP; proposals submitted by any other means will be disregarded. Detailed instructions regarding registration and proposal submission via DSIP are provided in the DoD SBIR Program BAA.

Technical Volume (Volume 2)

The technical volume is not to exceed 20 pages and must follow the formatting requirements provided in the DoD SBIR Program BAA. Do not duplicate the electronically-generated Cover Sheet or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 20-page limit.

Only the electronically-generated Cover Sheet and Cost Volume are excluded from the 20-page limit. Technical Volumes that exceed the 20-page limit will be reviewed only to the last word on the 20th page. Information beyond the 20th page will not be reviewed or considered in evaluating the offeror's proposal. To the extent that mandatory technical content is not contained in the first 20 pages of the proposal, the evaluator may deem the proposal as non-responsive and score it accordingly.

Content of the Technical Volume
The Technical Volume has a 20-page limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any other attachments. Refer to the instructions provided in the DoD SBIR Program BAA for full details on content of the technical volume.

Cost Volume (Volume 3)
The Phase I Base amount must not exceed $250,000. Costs for the Base must be clearly identified on the Proposal Cover Sheet (Volume 1) and in Volume 3.

Company Commercialization Report (CCR) (Volume 4)
Completion of the CCR as Volume 4 of the proposal submission in DSIP is required. Please refer to the DoD SBIR Program BAA for full details on this requirement. Information contained in the CCR will be considered by DHA during proposal evaluations.

Supporting Documents (Volume 5)
DHA SBIR will accept a Volume Five (Supporting Documents) as required under the DoD SBIR Program BAA.

Fraud, Waste, Abuse (Volume 6)
DHA SBIR will accept a Volume Six (Fraud, Waste, and Abuse) as required under the DoD SBIR Program BAA.

PHASE II PROPOSAL GUIDELINES
Phase II proposals may only be submitted by Phase I awardees. Phase II is the demonstration of the technology found feasible in Phase I. All DHA SBIR Phase I awardees from this BAA will be allowed to submit a Phase II proposal for evaluation and possible selection. The details on the due date, content, and submission requirements of the Phase II proposal will be provided by the DHA SBIR PMO. Submission instructions are typically sent toward the end of month five of the Phase I contract. The awardees will receive a Phase II window notification via email with details on when, how and where to submit their Phase II proposal.

Small businesses submitting a Phase II Proposal must use the DoD SBIR electronic proposal submission system (https://www.dodsbirsttr.mil/submissions/login). This site contains step-by-step instructions for the preparation and submission of the Proposal Cover Sheets, the Company Commercialization Report, the Cost Volume, the Technical Volume, Supporting Documents, and Fraud, Waste, and Abuse certificate.

The DHA SBIR Program will evaluate and select Phase II proposals using the evaluation criteria in the DoD SBIR Program BAA. Due to limited funding, the DHA SBIR Program reserves the right to limit awards under any topic and only proposals considered to be of superior quality will be funded.

Small businesses submitting a proposal are required to develop and submit a Commercialization Strategy describing feasible approaches for transitioning and/or commercializing the developed technology in their Phase II proposal. This plan should be included in the Technical Volume.

The Cost Volume must contain a budget for the entire 24-month Phase II period not to exceed the maximum dollar amount of $1,100,000. These costs must be submitted using the Cost Volume format (accessible electronically on the DoD submission site), and should be presented side-by-side on a single Cost Volume Sheet.

DHA SBIR Phase II Proposals have six Volumes: Proposal Cover Sheets, Technical Volume, Cost Volume, Company Commercialization Report, Supporting Documents, and Fraud, Waste, and Abuse. The Technical Volume has a 40-page limit including: table of contents, pages intentionally left blank, references, letters of support, appendices, technical portions of subcontract documents (e.g., statements of work and resumes) and any attachments. Do not include blank pages, duplicate the electronically-generated Cover Sheets or put information normally associated with the Technical Volume in other sections of the proposal as these will count toward the 40-page limit.

Technical Volumes that exceed the 40-page limit will be reviewed only to the last word on the 40th page. Information beyond the 40th page will not be reviewed or considered in evaluating the offeror's proposal. To the extent that mandatory technical content is not contained in the first 40 pages of the proposal, the evaluator may deem the proposal as non-responsive and score it accordingly.

DISCRETIONARY TECHNICAL AND BUSINESS ASSISTANCE (TABA)
The DHA SBIR Program does not participate in the Technical and Business Assistance (formally the Discretionary Technical Assistance Program). Contractors should not submit proposals that include Technical and Business Assistance.

The DHA SBIR Program has a Technical Assistance Advocate (TAA) who provides technical and commercialization assistance to small businesses that have Phase I and Phase II projects.

EVALUATION AND SELECTION
All proposals will be evaluated in accordance with the evaluation criteria listed in the DoD SBIR Program BAA.

Proposing firms will be notified of selection or non-selection status for a Phase I award within 90 days of the closing date of the BAA.

Refer to the DoD SBIR Program BAA for procedures to protest the Announcement.
As further prescribed in FAR 33.106(b), FAR 52.233-3, Protests after Award should be submitted to:

Ms. Micaela Bowers
SBIR/STTR Contracting Officer
U.S. Army Medical Research Acquisition Activity
Phone: (301)-619-2173
Email: micaela.l.bowers.civ@mail.mil

AWARD AND CONTRACT INFORMATION
Phase I awards will total up to $250,000 for a 6 month effort. Phase I contract awards will be awarded as Purchase Orders indicating the Technical Point of Contact. Phase II awards will be a Firm Fixed contract with the Contracting Officer Representative and other contracting staff identified.

ADDITIONAL INFORMATION

RESEARCH INVOLVING HUMAN SUBJECTS, HUMAN SPECIMENS/DATA, OR ANIMAL RESEARCH

The DHA SBIR Program highly discourages offerors from proposing to conduct Human Subjects, Human Specimens/Data, or Animal Research during Phase I due to the significant lead time required to prepare regulatory documentation and secure approval, which could substantially

delay the performance of the Phase I award. Prior to contract award when an IRB is indicated, proposers must demonstrate compliance with relevant regulatory approval requirements that pertain to proposals involving human subjects, human specimens, or research with animals. While technical evaluations will not be negatively impacted, evaluations requiring IRB approval may delay the start time of the Phase I award. If necessary approvals are not obtained within two months of notification of selection, the decision to award may be terminated.

Offerors are expressly forbidden to use, or subcontract for the use of, laboratory animals in any manner without the express written approval of the US Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO). Written authorization to begin research under the applicable protocol(s) proposed for this award will be issued in the form of an approval letter from the USAMRDC ACURO to the recipient. Modifications to previously approved protocols require re-approval by ACURO prior to implementation.

Research under this award involving the use of human subjects, to include the use of human anatomical substances or human data, shall not begin until the USAMRDC's Office of Research Protections (ORP) provides formal authorization. Written approval to begin a research protocol will be issued from the USAMRDC ORP, under separate notification to the recipient. Written approval from the USAMRDC ORP is also required for any sub-recipient that will use funds from this award to conduct research involving human subjects.

Research involving human subjects shall be conducted in accordance with the protocol submitted to and approved by the USAMRDC ORP. Non-compliance with any provision may result in withholding of funds and or termination of the award.

CYBERSECURITY CONSIDERATIONS

Appropriate cybersecurity considerations should be implemented at Phase III (or earlier if specified) for the potential transition of software and connected devices to be considered for future fielding. For initial information, please see the below reference to the *DoD Cybersecurity Reference and Resource Guide*.

DoD Cybersecurity Reference and Resource Guide
https://dodcio.defense.gov/Portals/0/Documents/Cyber/2019%20Cybersecurity%20Resource%20and%20Reference%20Guide_DoD-CIO_Final_2020FEB07.pdf

PHASE II ENHANCEMENTS

Through a Phase II Enhancement Program, the DHA SBIR Program provides matching SBIR funds to expand an existing Phase II contract able to attract investment funds from a DoD Acquisition Program, a non-SBIR government program, or eligible private sector investors. Phase II Enhancements allow an existing DHA SBIR Phase II contract to be extended for up to one year to perform additional research and development tasks. Phase II Enhancement matching funds will be provided on a dollar-for-dollar basis up to a maximum $550,000 of SBIR funds. All Phase II Enhancement awards are subject to a review process, availability of funding, and the successful negotiation and award of a Phase II Enhancement contract modification.

WAIVERS

In rare situations, the DHA SBIR Program allows for a waiver to be incorporated allowing federal facility usage for testing/evaluation. A waiver will only be permitted when it has been determined that no applicable U.S. facility has the ability or expertise to perform the specified work. The DHA SBIR

Program has the right of refusal. If approved, the DHA SBIR PMO will assist in establishing the waiver for Program Manager and Contracting Officer approval. If approved, the proposer will subcontract directly with the federal facility and not a third party representative.

DHA SBIR 22.1 Phase I Topic Index

DHA221-001 TITLE: Prolonged Care: To Demonstrate a Medicated Combat Tourniquet Capable of Wound Infection Treatment Delivery

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: To reimagine the current fielded tourniquet beyond prevention of exsanguination and demonstrate next generation designs capable of delivering treatment for the prevention of infection in a prolonged care setting. The technology must retain or improve upon the original functionality and shall be in an easy-to-use format, require minimal instrumentation, lightweight, and compatible with prolonged care. The treatment delivery approach should enable deep tissue penetration of, but not limited to, antimicrobial agents post-compression towards the wound bed. The end goal for this effort is to assemble a system of systems to prevent the development of infection in an austere environment when the provision of surgical intervention is delayed over 72 hours (hrs).

DESCRIPTION: Multi-domain operations (MDO) of the future anticipate division-on-division combat operations with causality volumes and medical intervention times that mirror what was observed in WWI and WWII. In MDO, the deployment of anti-access and area denial (A2AD) technologies will not only limit evacuation to degrade the Golden Hour timeline for medical support but also constrain medical resupply, which will leave wounded Warfighters and first line medical support providers stranded in prolonged care (PC) scenarios for unknown durations. Furthermore, repeated events of mass casualty and greater dependency on PC (limited resources while being mobile) will increase the number of deaths from wounds as the infection rate will rise in wounds within 72hrs and beyond as was observed in previous conflicts. Here, the amount of wound dressings and antibiotics needed to prevent infection from polytraumatic wounds based on current US military medical doctrine designed for “Golden Hour” doctrine are untenable in PC scenarios. As a result, the need for innovative solutions that are massively scalable and distributive (i.e. affordable and for all combatants) focused on amplifying self/ buddy care (i.e. fire and forget solutions that enable less supply to be carried for longer duration or the ability of one medical provider to provide care for a high number of wounded casualties) is an urgent need. Furthermore, adding materials to the improved first aid kit (IFAK) or combat lifesaver (CLS) bag presents significant challenges. The critical need for wound infections and sepsis mitigation at point-of-care and Role 1 is to design alternative and/or adjunctive solutions that prevent infection within the first 72 hrs following injury. One approach is to reimagine components of the IFAK as a system of systems to prevent the development of infection in polytraumatic wounds by extending treatment options over 72 hrs to increase Warfighter survivability until surgical intervention. This topic explores the development of the tourniquet not only as hemorrhage control device but also as a new aspect of treatment, as a drug delivery device as well to specifically meet the need for immediate administration of infection treatment at point of injury to prevent infection in prolonged care settings.

Exsanguination (i.e. bleeding to death) and combat wound infection are the most common causes of death from survivable wounds in the history of combat. Tourniquets have been an effective means of controlling exsanguination of compressible trauma on the battlefield and in pre-hospital care to limit mortality and morbidity. Unfortunately, the evolution of tourniquets over time has been unremarkable relative to the many advances of modern medicine. According to the Tactical Combat Casualty Care (TCCC) guidelines, the initial response to penetrating battlefield trauma is to stop major hemorrhage with pressure, tourniquet, and wound packing. Wound packing includes hemostatic agents along with broad-spectrum, systemic battlefield antibiotics to prevent infection followed by casualty evacuation within the hour if the battlespace is mature. Studies have established prolonged application of tourniquets contributes to ischemic-reperfusion injury and microvascular dysfunction that accompanies altered trauma physiology such as shock and sepsis. Furthermore, prolonged tourniquet application significantly reduces

systemically administered antibiotics from penetrating soft-tissue further complicating the infection resolution process. Lessons both from OIF and OEF and from civilian trauma is that “brief” application of tourniquets is generally “safe”. Current research and development on tourniquets are focused on developing smart tourniquets with pressure sensors and describing “application” duration.

Another arm of the problem is that the timing of antibiotic treatment significantly correlated with infection development process. Animal studies of open fractures revealed that early antibiotic treatment and surgical debridement within two hours prevented infection, but delays in antibiotics and surgery after two hours significantly increased the development of infections. These observations were validated in retrospective clinical studies in civilian trauma involving open fractures and further studies have revealed that administering antibiotics immediately after traumatic injury reduced infection rates significantly (i.e. 7% of infection if treated within the hour to 28% if treated after 1.5 hours). This paradigm of casualty management was successful in recent operations where medical evacuation to a higher echelon of care was possible within hours of traumatic injury. However, the conceivable lack of a reasonable timeframe for medical evacuation in large scale combat operations requires the adaption of PC to the new operational environment to meet the balanced need for ease-of-use, scalability, longevity treatment, and efficiency of treatment delivery focused on point-of-care and Role 1 care.

The ultimate goal of the technology in this request is, but not limited to, to combine exsanguination prevention and antibiotic delivery in one-step at the earliest time possible after injury. In doing so, this convergent technology should prevent infection development as decolonization measure of the wound bed (maintain agents of infection below 10^5 threshold) by rapid treatment prior to ischemic-reperfusion injury (within 1.5hrs). This is not meant to replace systemic treatment upstream of tourniquet application according to current CPG.. The intent here is also to overcome compliance issues with combat wound medication packet (CWMP) usage, extend CWMP dose for later use, and ultimately increasing survivability for surgical intervention at point-of-injury and Role 1. The aim of this SBIR is to develop a technology with commercial viability that addresses the multidimensional problems of traumatized tissue biology and to accelerate the next generation of innovations that combine, but not limited to, sensors, treatment (i.e. small molecule-based antibiotics, tissue regeneration, pain management, immune modulators, monoclonal antibodies and/or bacteriophage) delivery features and sleeve/chamber features for bio-containment. When proposing a technology, it is paramount, but not limited to, to consider the factors below:

1. The starting technology must plan to have FDA or equivalent device clearance.
2. The original functionality of the tourniquet cannot be compromised or traded off for a new feature.
3. The original packing weight (2.7 oz) and dimensions (LxWxH- 6x2x1.5 in) should be at or near current fielded product but no more than 10% increase in weight or dimensions.
4. Modular designs with a library of medications incorporating exchangeable cartridges, microneedles, micropumps, catheters, gels… etc. are welcomed, but should describe a ruggedization plan and durability of design to include mechanical systems that require minimal logistical support.
5. Designs must have a manual fail-safe backup option for motorized or automated designs for active delivery.
6. Treatment of choice shall cover a wide array of infectious organisms but not limited to, small molecule-based antibiotics, metal ions, lantibiotics, natural products, bacteriophages, antibodies, polymers, nano-fibers/sponges, antimicrobial peptides, and or any pathogen agnostic treatment. Stable formulations with long shelf-life (18 month +) should be considered.
7. Other treatments such as analgesics for pain management, regenerative, and immune modulators are optional.
8. Modular designs to include bio-containment of wounds such as severed limbs in the form of a convertible sleeve or chamber are optional.

9. Built in sensors are optional.
10. Ease of applications, ability to withstand water, hot and cold temperatures and minimal storage conditions will be factored in the nomination process.
11. Engineering solutions overall should require minimum logistical support and should be compatible with applications in extreme environments including hot and cold temperature.

PHASE I: Given the short duration of Phase I and the high order of technology integration required, Phase I should focus on system design and development of proof-of-concept prototypes that address the treatment delivery requirement. Proposals may include different formulations of treatment. Prototypes may combine "classes" of applications into different "sets" of designs. At the end of this phase, fabricated prototypes should demonstrate feasibility, proof-of-concept and establish "release profile", using relevant testing platforms for the proposed technology. This phase should down-select promising design as well as identify a pre-clinical animal model, such as, but not limited to, hemorrhagic shock, open fracture or soft tissue wounds with and without infection for use in Phase II. Evaluation of the product's efficacy for controlling infection with antimicrobial activity must include data for the first 6, 24, 48, and 72 hours at a minimum, if not longer. The above time points do not represent tourniquet application on subjects but used as a bench mark and quantify duration of decolonization of wound bed and prevention of infection.

PHASE II: During this phase, the lead integrated system should be further refined from proof-of-concept into a viable product. Further optimization of the technology for deep penetration of treatments into the traumatized wound bed should be demonstrated during this phase. Qualitative and quantitative outcomes of product with regards to hemorrhage control, prevention of infection, and/or decolonization by invading organisms must be demonstrated as specific performance characteristics of the product compared to standard issued CAT. This testing should be controlled, and rigorous. Testing and evaluation of the prototype to demonstrate operational effectiveness in simulated environments shall be demonstrated. Stability of product in an austere environment should be evaluated to include extreme conditions (i.e. extreme heat, cold, wet environment). This phase should also demonstrate evidence of commercial viability of the product. Accompanying application instructions, simplified procedures, and training materials should be drafted in a multimedia format for use and integration of the product into market. Price estimate and comparison analysis for new design relative current fielded equipment and treatment shall be provided to forecast the potential cost of product. The offeror may develop a regulatory strategy for FDA clearance early to guide product development early on. Offeror may consider a pre-pre-submission communication with the FDA as an early communication for guidance.

PHASE III DUAL USE APPLICATIONS: The ultimate goal of this phase is to secure FDA clearance by developing non-DOD partnerships to demonstrate and commercialize a technology enabling the prevention of infection in wounded service members from infected traumatic combat wounds and control of hemorrhage under PC.. The global market for wilderness medicine and first responder technologies is worth over 100 billion dollars.. Appropriate partnerships to advance the technology above is encouraged at this stage to enable a commercial off-the-shelf solution for market analysis by USAMMDA WEMT or other DOD entities. Alternatively, further development, testing and evaluation of the medicated tourniquet product developed by phase II of this SBIR can be supported by CDMRP, JWMRP, and other DOD opportunities and partnerships. This effort should seamlessly be integrated into the TCCC paradigm of initial response to trauma. Once developed and demonstrated, the technology can be used both commercially in civilian or military settings to save lives. The selected contractor shall make this product available to potential military and civilian users.. If product is transitioned into Acquisition Programs of Record, the Government may work with offeror to further refine and harmonize design with other relevant products.

REFERENCES:

1. Kragh JF Jr and Dubick MA. Battlefield tourniquets: lessons learned in moving cur- rent care toward best care in an army medical department at war. US Army Med Depart J 2016:29–36.
2. Penn-Barwell JG, et al. Early antibiotics and debridement in- dependently reduce infection in an open fracture model. J Bone Joint Surg Br 2012;94:107–112.
3. Lack WD, et al. Type III open tibia fractures: immediate antibiotic prophylaxis minimizes infection. J Orthop Trauma 2015;29: 1–6.
4. Mangum LC, et al. Duration of extremity tourniquet application profoundly impacts soft-tissue antibiotic exposure in a rat model of ischemia-reperfusion injury. Injury 2019;50: 2203-2214.
5. Benov A, et al. Antibiotic treatment-what can be learned from point of injury experience. Mil Med 2018;183: 466–471.

KEYWORDS: MDO, tourniquets, drug delivery, wearable, trauma, prolonged care

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DHA221-002 TITLE: Scalable Multi-person Hearing Protection Device Fit-testing System

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: Develop a system that can simultaneously fit-test multiple people with hearing protection devices (HPDs). The system should be usable in clinical and non-clinical settings to quickly test the fit of HPDs from various manufacturers.

DESCRIPTION: The Hearing Conservation Program is the largest occupational health program in the Department of Defense (DOD), crucial because the majority of military members are exposed to hazardous noise. Civilian personnel are also assigned to the program when subject to noise exposure associated with work such as aircraft, vehicle, or ship maintenance and other activities. One of the methods used to reduce noise exposure and prevent occupational hearing loss is the use of hearing protection devices (HPD). Until recently, the only way to ensure proper fit of hearing protection was to perform a real ear attenuation threshold (REAT) test in an audiometric booth. This type of testing is time- and labor-intensive. In recent years, commercial systems have been developed to enable HPD fit-testing outside of an audiometric booth. The Department of Defense Instruction 6055.12, Hearing Conservation Program, cites fit-testing as a best practice. Recent studies performed at Navy and Marine Corps accession points to determine the viability of large-scale HPD fit-testing on large numbers of recruits determined that testing at 500, 1000, and 2000 Hertz provided good fit-test results. However, these studies also found that on initial fitting, 55% of participants did not receive adequate protection; some (3.75%) new recruits could not achieve an adequate personal attenuation rating (PAR) with their issued HPDs and had to be offered alternative HPDs. Researchers concluded that adequate protection depends upon proper fit of the issued HPD as well as the quality of initial training (Federman & Duhon, 2016). A more recent study showed earplug PARs were highly variable across study participants; compared to participants with normal hearing, those with hearing loss had significantly lower PARs (Ullman et al., 2021). Other studies have shown that low levels of background noise do not affect PARs, which supports the feasibility of performing HPD fit-testing in the field (Gallagher et al., 2016). One study reported good results with fit-testing using modified ear cups for the Benson medical headphones (TDH-39) (Stefanson & Ahroon, 2019).

In 2018, the Acoustical Society of America (ASA) approved a national consensus standard (ANSI/ASA S12.71-2018) for field attenuation estimation systems (FAES) to measure HPD PAR. Various technical approaches can be used to determine attenuation, including non-audiometric booth REAT tests, field microphone in real ear tests, loudness balance tests, and audiometric booth REAT tests designed for multi-person booths. To date, only one FAES meets the ASA standard for individual HPD fit-testing, but the system can only be used to test one manufacturer’s HPDs. The Department of Defense needs an HPD fit-test system that is scalable to allow testing of at least one person, with the ability to simultaneously fit-test multiple people (up to100 or more). The device(s) should be portable to allow for testing in a variety of settings, including clinics, quiet office spaces, in the field, aboard ships, and with mobile audiometric testing platforms. The device(s) must be able to fit-test most commercially available earplugs. PAR should be calculated using 3, 5, or 7 frequencies, with an overall PAR and individual PAR values per octave band.

PHASE I: Phase I awardees will conceptualize and design an innovative system to rapidly fit-test multiple people at once and provide individualized PARs. The system must be usable in clinics, training classrooms, aboard ship, and in field locations such as firing ranges. Solution could include hardwired equipment or be an application (app) which uses existing methods to generate auditory signals. Designs should incorporate commercially available electronic and computer components. Software systems should

have capability to store and forward results for upload into occupational health records, safety records and military medical readiness systems. Individual files would include personally identifiable information but no personal health information. Data must be mineable and able to be packaged individually, by commands or bases for the military, and by company and work centers for industry. The system's power supply should use standard U.S. power and be designed to operate by battery with a minimum battery life of 4 hours and quick recharging capability. Batteries should not require specialized handling. Design should use standard ruggedization comparable to regular safety instruments such as sound level meters. Equipment should be able to operate in normal hot and cold environments, but does not need to be designed for extreme environments. Due to military constraints, wifi and Bluetooth-enabling should not be the only way to connect multiple individuals to the system.

Phase I deliverables: A concept and demonstration that the theoretical concept is valid for fit-testing hearing protection for multiple individuals simultaneously. Concepts will be evaluated on the number of individuals the system can test simultaneously, the speed of testing, and portability of any equipment.

PHASE II: Using results from Phase I, Phase II will develop, fabricate, and validate a prototype of the multi-person fit-testing system. Phase II initial goal will be to develop and fabricate a system capable of fit-testing multiple people at once. The second goal will be to validate the fit-testing system under an IRB-approved research protocol followed by HRPO-approval. Research does not need to be conducted at a DoD facility and can use a civilian IRB. A third goal will be to demonstrate system ability to conduct fit-testing in a variety of settings and with background noise. One fully functional prototype will constitute the fourth deliverable, accompanied by validation test reports and other relevant reports and designs. Factors used to assess the solution will be:

1. The number of people able to be tested at once where greater numbers are of higher value.
2. Speed of testing where faster is better.
3. Fidelity of test results where smaller levels of uncertainty are better.
4. Sensitivity and specificity where accuracy is valued more than precision.
5. Level of background noise under which the system can be used.

PHASE III DUAL USE APPLICATIONS: Implement any design changes from phase II. Develop production processes, training software, and manuals for the product system. Final product configuration should minimize footprint and weight for portability and ease of storage. The primary target users for the product are companies with large hearing conservation programs. The ability to test multiple people quickly and at the same time will increase the desirability of the product to industry. System would be further enhanced if it requires minimal training and can be used by non-medical personnel. This system could be marketed to many industrial, transportation, mining, and construction companies to improve their hearing conservation programs and increase compliance with the Occupational Safety and Health Administration and other regulatory requirements. In addition, the work may result in technology transition to an Acquisition Program managed by the Service Product Developers. The contractor can also propose product use to the military Services. Connectivity to DoD safety systems should be able to be accomplished as the system becomes GOTS/COTS. Utility of the product will be enhanced if the device is easily portable and requires minimal supervision to produce repeatable results. The capability to administer HPD fit-testing to large groups of people at once will ensure that personnel exposed to noise can be properly trained and fitted with HPDs in an efficient and effective manner.

REFERENCES:

1. ANSI/ASA S12.71-2018 Performance criteria for systems that estimate the attenuation of passive hearing protectors for individual users.
2. Federman J, Duhon C. The viability of hearing protection device fit-testing at navy and marine corps accession points. Noise Health [serial online] 2016 [cited 2017 Jan 5];18:303-311 http://www.noiseandhealth.org/text.asp?2016/18/85/303/195806.

3. Gallagher H, Murata TK, McKenna EA, et al. Personal Attenuation Ratings reported using Fit Check Solo: Is background noise a concern? 5th Joint Meeting of the Acoustical Society of American and the Acoustical Society of Japan 2016.
4. Stefanson EW, Ahroon WA. Computer-controlled audiometer's application as an earplug fit-testing tool. The Journal of the Acoustical Society of America 140, 3274 (2016).
5. Ullman ED, Smith LM, McCullagh MC, et al. Hearing loss as a predictor for hearing protection attenuation among miners. Occup Environ Med 2021;78:371–376.

KEYWORDS: hearing, hearing loss, hearing protection, noise, personal protective equipment, hearing protector fit testing, injury prevention, personal attenuation rating

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DHA221-003 TITLE: Olfactory Neuroepithelium Functional Diagnostic Tool

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: To develop a non-invasive diagnostic device that can be used to determine the cellular and functional characteristics of olfactory neuroepithelium with limited or no anesthesia. The device should be able to determine thickness of mucus on top of the mucosa and then be able characterize important properties of the cellular layers of the olfactory cleft mucosa as has been demonstrated with optical coherence tomography (OCT) and confocal laser endomicroscopy (CLE) in the pulmonary tract. This would include proportion of supporting cells, fibrosis, and neuronal composition. The ability to assess olfactory neuroepithelium cellular structure enables assessment of the degree of insult from injury, leading to better treatment and improved patient outcomes. The resulting diagnostic device (medical product) will be employed at level III or IV care for diagnostic assessments after injury.

DESCRIPTION: Modern warfare exposes members to significant volatile inhalational injury risk. Many members return from deployments reporting a diminished sense of smell from burn pit exposure, oil field vapors, exposures to minute quantities of harmful battlefield chemicals, and other onsite/uncharacterized chemical exposures. The current COVID pandemic has significantly increased the number of permanent hyposmia/dysosmia cases occurring in active-duty personnel to the point of olfactory dysfunction becoming a concerning risk for duty limitation[8]. As a poignant example of this, Joint Base San Antonio Ear, Nose and Throat (ENT) referrals for active duty olfactory dysfunction have gone from a handful a year, to 2-3 per week. Modern testing techniques for olfactory dysfunction currently are very elementary and produce poor quality objective data on which to base treatments. These tests simply report a percent correct of common odors recognition with no insight regarding mechanism of injury. This ability to differentiate is critical to ensure optimal therapeutic strategy. For example, anosmia due to allergies or sinusitis responds to steroids and other anti-inflammatory therapies to reduce edema in the local microenvironment. This contrasts with COVID associated anosmia, which is due to injury to supporting cells, resulting in neuronal death. COVID associated anosmia does not respond to anti-inflammatory therapies and likely requires therapies targeting neuronal regeneration.

The primary role of olfaction in the military is for supporting “threat assessment.” The following career fields have expressed concerns to us over the years regarding loss of sense of smell: Military Police and Security Personnel (smell of alcohol on breath, vapors from an investigation scene), Firemen (smell of smoke, methane, other volatiles), Food Safety personnel (responsible for preventing food poisoning related to feeding vast numbers of personnel/trainees), Medical Workers (rely on sense of smell for sterility assessment, diagnostics), and Flight Line personnel (Jet Fuel leakage and other industrial chemical hazards). Outside of basic sense of smell tests and subjective questionnaires, there are no reliable imaging tools to assess any key characteristic of the sense of smell. We propose to develop a new technology for olfactory neuroepithelium assessment that will include an objective assessment of the health and viability of the olfactory cleft mucosa. Specifically, we desire a technology that can differentiate the following layers in terms of thickness, and other key material properties: mucus, epithelium, lamina propria, and potentially the olfactory bulb. We are impressed with the potential of both OCT (Optical Coherence Tomography) and CLE (Confocal Laser Endomicroscopy) technologies for this capability, and are open to new and novel technological solutions that may offer better solutions for improving patient outcomes. With this innovation, health care providers will be provided a tool to obtain essential objective data required to screen for disease and to recognize when treatments are having a subclinical effect.

PHASE I: During Phase one, determine and define the efficacy of the proposed technology that can determine layer thickness and material properties of the olfactory neuroepithelium. The proposed technology will have not have the potential to damage the mucosa or chemosensory structures being examined. Design/develop an innovative concept along with limited testing of potential materials. The product will be evaluated by Otolaryngologists, Allergists and Neurologists at role 3-4 clinical settings. Design requirements may include ease of use, minimal equipment or activation process and be delivered in a minimally invasive manner. It must be mobile, not cause pain or bleeding, able to be used without physically disturbing the structure it is measuring, have ease of storage (heat and cold tolerance) and be applied in vivo (no biopsy required to perform measurements). Demonstration of a prototype is desirable with some early in vitro data using rodent cultures. The product will report key histologic metrics to include: epithelial layer thickness, proportion of supporting cells, neuronal density and organization and inflammatory burden in the spectrum from normal olfaction to anosmia. The product should have function that meets existing output measures of similar technology applied to pulmonary respiratory mucosa.

PHASE II: Detail analysis of the selected device that will include optimal performance properties that are safe and perform according to the specifications listed below. The device should be designed to be utilized to minimize or avoid causing severe discomfort, bleeding, or mucosal disruption with use. In vivo efficacy will be established murine models of anosmia. Validation of efficacy will be gross histologic confirmation.The device will report key histologic metrics to include: epithelial layer thickness, proportion of supporting cells, neuronal density and organization and inflammatory burden in the spectrum from normal olfaction to anosmia. Validation of efficacy will be gross histologic confirmation. Clinical experts with insight into olfactory dysfunction and relevant patient populations should be consulted during optimization and animal validation.

PHASE III DUAL USE APPLICATIONS: Potential commercial and clinical partners for Phase III and beyond should be identified, and a detailed explanation should be provided for how the small business will obtain a monetary return on investment. Awardees will seek to develop a useable prototype for DOD role 3 and 4 environments. They will develop a strategy to lock in the final design (freeze and bridge the gap between laboratory-scale innovation and entry into a recognized FDA regulatory pathway leading to commercialization of the product that will be made available for purchase by the military health system and private sector. Close communication with military surgeons on the development on the product should be considered. Additional customers will likely be academic referral centers capable of validating a large number of patients with olfactory complaints. Functional prototypes will enable development and funding of clinical trials to assess efficacy of the devices and optimize functionality, performance, and safety. Small business should have a strategy in place to secure funding from the private sector and partnering with other medical device companies as needed to reduce costs and risk while improving product availability and capabilities. Imaging companies in the OCT space (e.g. OptoVue) are likely partners to streamline development and testing in humans. Given the worldwide impact of anosmia, funding should be sought from the World Health Organization (WHO).

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KEYWORDS: Olfactory Dysfunction, Anosmia, Hyposmia, Dysosmia, Burn Pit

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DHA221-004 TITLE: Blind 3D Kinematic Measurement of High-Rate Complex Surface Deformation

OUSD (R&E) MODERNIZATION PRIORITY: General Warfighting Requirements (GWR)

TECHNOLOGY AREA(S): Bio Medical

OBJECTIVE: Develop and demonstrate technologies capable of measuring complex surface response kinematics at the interface between the torso and body armor system.

DESCRIPTION: Body armor systems can be comprised of hard and soft materials which are designed to prevent ballistic projectile penetration into underlying surfaces and improve armor performance. Defeat of ballistic threats are typically accompanied with armor system back face deformation (BFD) into the underlying torso. Current armor system performance requirements include deformation depth limits, measured by the residual deformation impression in a clay substrate backing. While penetration of the ballistic threat may be stopped by the armor system, the ballistically induced BFD could induce injury to the wearer. Advanced material development advancements have produced armor systems capable of defeating increased threats, but with various BFD characteristics. Unfortunately, the backing material obscures visual observation of back face surfaces.

To establish human injury risk due to blunt insults, the Medical Research & Development Command research laboratories need the ability to accurately characterize the high-rate response surface kinematics which occur at the outer body armor system and underlying tissue interface when ballistic threats are defeated (i.e., no tissue penetration). An innovative approach is needed to measure and record these kinematics during ballistic exposures. This technical solution would provide medical researchers with a critical tool needed to define human injury mechanisms and tolerances associated with blunt exposures. The approach should be independent of backing material used, and should not influence the armor's performance or deformation response. The measurement system should provide a time-history surface deformation response along with associated kinematic parameters. The surface response parameters should include deformation depths, velocities, and accelerations, cross-sectional areas of deformations at variable deformation depths, deformation volumes, and their change rates. Analytical data post-processing techniques are required to extract and provide the response kinematic parameters and a computational visualization of data collected during dynamic test events.

Due to the high speed of ballistic induced insult onto the armor system, the data acquisition rate should be greater than 100 kilohertz (kHz). Deformation depth measurement resolution should be at least 1 millimeter (mm) with a sensitivity of 0.5 mm. The sensing surface should cover a minimum area of 400 by 400 mm; a single sensing array should cover the surface area of the armor systems. Sensing array spacing should be less than 5 mm. The sensing material should be flexible to account for the complex curvature of armor surfaces and backing materials. Unless the armor system fails to prevent ballistic threat penetration, the ideal measurement system should recover and be reusable. Current rigid armor testing protocols require ballistic impacts at three distinct locations. The deformation measurement system should capture these three events without need for removal. During exploratory and developmental testing, armor systems could be tested in more than three distinct locations. Methods to calibrate and verify system operation will be needed. If successful, this innovative technology will allow researchers to ascertain injury risk associated with individual armor system BFD during successful ballistic defeat. Use of this system could be employed in multiple medical research programs and armor systems research, development, and acquisition by the military, law enforcement organizations, etc.

PHASE I: The main goal of Phase I is a feasibility study in the development of a high-rate surface response sensor system. Initially, to prove feasibility, a physical, electronics, optical and circuit design of

the sensor system should be completed as the first deliverable. The electronic and circuit designs should include commercially available electronic, computer, and optical components, or components that can be fabricated easily and without extraordinary expense. The physical design of the surface response sensor should not exceed 2 mm thickness and cover a 400 mm by 400 mm area. The material should be lightweight and highly flexible in order to conform to complex and rapidly changing surface profiles, without altering the performance of armor systems and their deformations. The sensing array spacing within the sensor element should be less than 5 mm. A second deliverable is a data acquisition system and software capable of operating and sampling the surface response sensor system at a sample rate of 100 kilohertz. Appropriate anti-aliasing filters should be integrated into the data acquisition system. The associated software should provide ability to control power to the sensor system and provide data collection trigger options (manual, external source, and sensor threshold activated), and ability to store and view the collected data. A third deliverable is a data processing software capable of performing the needed post-processing of the sensor system data to extract the surface response kinematic metrics and provide imaging algorithms for displaying digital visualization animations of the surface response at various playback speeds. The response metrics include parameters such as, deformation distance, velocity, accelerations, strain rate, area, and volume at various surface points. The animation files should be easily recorded and exportable in commercial video formats to other commercial software programs. The post-processing software should provide a means for exporting the surface response kinematics data into commercially compliant software files. The fourth deliverable is a description of the surface response sensor system, the accompanying data acquisition system and supporting software systems. This is necessary because if the innovative technologies anticipated to accomplish the high-rate surface response data acquisition and associated data density. A detailed software schematic must be produced to indicate the computational path and logic in sensing, triggering, data acquisition, metric extraction, and data visualization algorithms. Specific existing software, or a plan to program new software, must be identified that can accomplish each step involved in the software path.

PHASE II: The overall objective of Phase II is to produce a fully operational prototype high-rate surface response sensor system, and required data acquisition and software system(s), capable of collecting high-rate surface response kinematics of a ballistically driven surface and through data post-processing, extract the surface response kinematic metrics and visually display response surface animations of the collected data. Testing of improvements and changes is then encouraged in order to take advantage of the state-of-the-art in electronics, optics, data acquisition technologies, computers, and software. At this early stage, data can be generated by testing with inanimate phantoms such as placing the sensor system over a heavily padded surface (flat and curved) and striking the sensor material with a blunt object of known and different surface geometries such a baseball bat or other projectile. The aim is to mature the software programming and data post-processing algorithms to identify the known surface geometry and to test the robustness of the surface sensor technology and the required electrical wiring harnesses and connectors. This system and software should be tested extensively with inanimate phantoms. Modifications to the sensor system electronics, optics, data acquisition function, software and/or data post processing algorithms should be made at this point. Next, the focus should shift to the production of a fully functional prototype high-rate surface response sensor system in the desired form factor, complete with the computer software needed to perform data acquisition and all functions for collecting, archiving, retrieving the acquired data, extracting surface response kinematics, and data visualization animations. This system should be demonstrated to acquire high-rate surface response data (such as, deformation distance, velocity, accelerations, strain rate, area, and volume) collected with inanimate phantoms when struck by blunt surfaces of known surface geometries. The system data acquisition system and associated software should have the ability to detect sensor system faults and to verify system functionality prior to data collection events. Sensor calibration techniques should be investigated and demonstrated, and calibration hardware and methodologies developed. One fully functional prototype will constitute the third deliverable, accompanied by user manuals, calibration procedure, validation test reports and other relevant reports and designs.

PHASE III DUAL USE APPLICATIONS: During a Phase III award, the awardee will work towards maturing the technology, software and manuals for system commercialization. This product is envisioned to be a stand-alone sensor technology capable of being integrated with other test systems to record complex, high-rate surface deformations. The final product is envisioned to consist of three major components, the sensing element(s), the data acquisition module, and software. Users may require multiple sensing elements as they may sustain damage in harsh test environments. Along with the accompanying software, this data will be processed to provide surface response kinematics such as, distance, velocity, accelerations, strain rate, area, and volume. Commercially, this technology and capability could be utilized in the automotive testing and development market, by recording structural deformations during crash testing, seating system development to capture seat surface deformations for improved comfort, endurance, and to investigate chronic back pain in at-risk populations such as long distance truck drivers. New developments in anthropometric test dummies could utilize this technology to record surface deformations of various body regions (abdomen, chest, etc) to record deformations during automotive crash testing in order to document injury risks. Current test dummy instrumentation systems measure chest deformation in discrete locations. This technology is directly applicable to military medical research, such as the Military Operational Medicine Research Program at the Medical Research and Development Command in their research efforts on human tolerance, specifically blunt trauma, as well as utility in the Military materiel research, development, and acquisition in the areas of non-lethal weapon and personal protective equipment development. If this technology is successful, it could be embedded into procurement and testing requirements for the research, development, testing, and acquisition of body armor systems. As such, this technology could be adopted by the National Institute of Justice for integration into their performance specifications for body armor systems used by law enforcement personnel. Commercially, this technology would then be widely used by commercial industries that develop and produce personal armor systems for the military, law enforcement, and private citizens, as well as companies that produce protective equipment such as torso and chest protectors used in numerous sporting activities.

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